REMARKS/ARGUMENTS

Claims 10-35 are active. Claim 10 has been amended to separately refer to combinations of Norovirus samples and antibodies or Sapovirus samples and antibodies and has been revised to include at least one limitation from claims 14-19 which were not rejected. New claims 31-35 finds support as described for prior claim 1. No new matter has been added. Favorable consideration of this amendment and allowance of this case are respectfully requested. The Applicants thank Examiner Li for withdrawing the prior rejections under 35 U.S.C. §112 and certain prior art rejections. The remaining prior art rejections are discussed below.

Rejection—35 U.S.C. 102

Claims 10-13 and 20 were rejected under 35 U.S.C. 102(b) as being anticipated by Hardy, et al., Virol. 217:252 on the grounds that the immunoelectron microscopy (IEM) reads on the composition of claim 10. This rejection is now moot in view of the amendment of these claims.

It would not apply to new claim 31. Hardy does not disclose a composition for use in IEM that has a pH ranging from 9.0 to 10.0. Hardy, page 253, 1st col. "Materials and Methods" indicates rNV particles were dissociated in 10 mM Tris (pH 9.0) prior to trypsin digestion to produce a *32K trypsin cleavage product.* This product is distinct from the purified *rNV particles* used for IEM, which according to Hardy (1995) were produced by expression in insect cells followed by purification on a sucrose gradient without exposure to high pH--see Hardy (1995), page 1694, 1st col. "Materials and Methods".

If there is a specific portion of Hardy et al. that discloses a composition at pH 9.0 to 10.0 for use in IEM containing Sapovirus or Norovirus in combination with the corresponding anti-virus antibody (other than at page 253, col. 1, which only describes

trypsin digestion in10mM Tris, pH 9.0), the Applicants invite the Examiner to point this out in Hardy, et al. or in the references cited by Hardy as describing the IEM procedures used (e.g., Nakata, et al., 1987, see page 253, col. 2, lines 11-12).

Assuming *arguendo* that the 32K trypsin cleavage product made using 10 mM Tris buffer at pH 9.0 was used in IEM described by Hardy in col. 2, this composition still would not anticipate the claim 31. The IEM procedure in col. 2 specifies that 0.5 to 1.0 μg of rNV (which is assumed to be trypsin-digested) were incubated with the monoclonal antibodies. These rNV particles presumably have been separated from the Tris pH 9.0 buffer because their quantity is specified by weight and not by concentration.

Moreover, even if 0.5 to 1.0 μg of a trypsin-digestion buffer having a pH of 9.0 containing an unknown concentration of rNV particles was used for IEM, it would have been diluted by 1:1000 with antibody following the procedure in col. 2 on page 253 of Hardy. Hardy is silent as to the pH of the diluting antibodies, but the Office has provided no reason to believe that the antibodies used to make the 1:1000 dilution have a pH of 9.0, and has not provided any reasoning explaining why a 1:1000 dilution of rNV particles and antibodies would have a pH within the range of 9.0 to 10.0 required by claim 31.

For each of these reasons, the Applicants respectfully submit that Hardy does not disclose the invention of claim 31 and therefore, this claim would not be subject to the prior rejection.

Rejection—35 U.S.C. 103

Claims 10-13, 20 and 22-23 were rejected under 35 U.S.C. 103(a) as being anticipated by Hardy, et al., Virol. 217:252, and Kitamoto, et al., J. Clin. Micro. 40:2459. This rejection is moot in view of the amendments above. It would not apply to new claim 31 for the following reasons.

Hardy does not disclose a pH 9.0 to 10.0 composition containing the required viral samples and anti-virus antibodies as detailed above. Moreover, Hardy processes stool samples in PBS prior to performing an antigen capture assay (page 253, 2nd col. "Detection of Norwalk virus antigen in stools", first paragraph) and cannot suggest or provide a reasonable expectation of success for the superior antigenic sensitivity obtained by specimen preparation at a higher pH as required by claim 31 and as disclosed in the paragraph bridging pages 4-5 of the specification.

Kitamoto also is silent about a composition having a pH ranging from 9.0 to 10.0 containing the components required by claim 31 and did not provide a reasonable expectation of success for the claimed methods which require this pH range. Accordingly, this rejection would not apply to new claim 31.

Rejection—35 U.S.C. §112, second paragraph

Claims 12 was rejected under 35 U.S.C. 112, second paragraph, as being indefinite. This rejection is moot in view of the amendments above. The Applicants respectfully submit that a Good's buffer could be titrated to the required pH. Moreover, the Applicants submit that the Good's buffers (Bicine, TAPS, CHES, CAPSO, and CAPS) shown in the attached table provide optimal buffering within the pH range of 9.0 to 10.0.

Conclusion

In view of the amendments and remarks above, the Applicants respectfully submit that this application is now in condition for allowance. An early notice to that effect is earnestly solicited.

Respectfully submitted,

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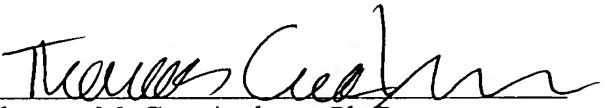

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